K958435 K952431

II 510(k) Summary

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PRODUCT NAME: Celsite® Pediatric Venous Port

TRADE NAME: Celsite® Pediatric Venous Port

CLASSIFICATION NAME: General Hospital Devices
Class III, 80 LJT,
Implanted Port & Catheter,
Intravascular, Infusion

SUBSTANTIAL EQUIVALENCE[1] TO:

510(k) number	Name	Applicant
K902401	CELSITE™ Implantable Drug Delivery System	Burron Medical Inc. (previous title of B. Braun Medical Inc.)
K942024	PORT-A-CATH LOW PROFILE IMPLANTABLE VENOUS ACCESS	PHARMACIA DELTEC INC.

DEVICE DESCRIPTION:

The CELSITE® Pediatric Venous Port is a implanted catheter system which allows safe, repeated access to the patient's bloodstream. The chamber and catheter design can be use for the administration of medications and fluids. B. Braun Medical, Inc. intends to introduce into interstate commerce Celsite® Pediatric Venous Port.

[1] The term "substantially equivalent" as use herein is intended to be a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act and relates to the fact that the product can be marketed without premarket approval or reclassification. Such a determination is not intended to be applicable to patent infringement suits or any other patent matter related to this product or the technology used to manufacture the product.

MATERIAL:

The CELSITE® Pediatric Venous Port is composed of materials have been tested in accordance with Tripartite Guidance for Plastics and determined to be suitable for the intended use of this product.

SUBSTANTIAL EQUIVALENCE:

B.Braun has marketed the single port CELSITE® since it's clearance by the FDA in 1991 (K902401). This device has the same materials and is similar in design to the previously cleared CELSITE® port.

The modification to the design is the size of the port. The ports cited as substantially equivalent to the other manufacturers pediatric port design. A review of the current literature and MDRs indicate that there are no additional risks or concerns associated with pediatirc port designs.

SAFETY AND EFFECTIVENESS:

The manufacturing site, B.Braun Celsa LG in France, has passed FDA inspection during this year.

Implanted ports for intravascular access have become quite common with tens of thousands implanted yearly. Considering the number of ports implanted yearly verses the number of MDRs, implanted ports have demonstrated themselves on the whole to be safe and effective devices.